PRUGEN, INC.
Pharmaceuticals

K082089/S1

Revised 510(k) Summary

JAN 13 2009

Date Prepared: January 9, 2009

1. **Owner's Name:**

PruGen, Inc.
8711 East Pinnacle Peak Road
Suite C-201
PMB 225
Scottsdale, AZ 85255

Contact Person:

Robert L. Knechtel
PruGen, Inc.
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2. **Proprietary Name:** PruMyx™ Cream
Common Name: Dressing, Wound & Burn, Hydrogel w/ Drug or Biologic
Classification Name: Dressing, Wound & Burn, Hydrogel w/ Drug or Biologic (Product Code FRO)

3. **Substantially Equivalent Devices:**

PruGen, Inc. believes that PruMyx™ Cream is substantially equivalent to the following currently marketed device: MimyX® Cream cleared under K041342.

4. **Device Description:**

PruMyx™ Cream is a non-sterile, semi-viscous emulsion intended for topical application. It is presented for both Prescription (requiring a physician diagnosis disease state) and over-the-counter (OTC) use.

5. **Intended Use of the Device:**

The prescription form of PruMyx™ Cream requires a physician diagnosis of a disease state and is indicated for the management and relief of the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. The OTC version of the device is indicated for general symptoms such as burning and itching associated with many common types of skin irritations. The device helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

6. **Summary of Technical Characteristics of Device compared to Predicate Devices**
All referenced predicate devices are non-sterile emulsions that are applied to relieve the symptoms of various dermatoses.

7. **Conclusions:**
Functional and performance testing has been conducted to assess the safety and efficacy PruMyx™ Cream and results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2009

PruGen, Inc.
% Robert L. Knechtel, M.D., J.D.
10 South LaSalle Street, Suite 3300
Chicago, Illinois 60603

Re: K082089
Trade/Device Name: PruMyx™ Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 7, 2008
Received: October 14, 2008

Dear Dr. Knechtel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) number (if known): K082089

Device Name: PruMyx™ Cream

Indications for Use:

FOR TOPICAL DERMATOLOGICAL USE ONLY

Description Rx Product:
Under the supervision of a healthcare professional, PruMyx Cream is indicated to manage and relieve the burning and itching experienced with various-types of dermatoses, including radiation dermatitis, atopic dermatitis and allergic contact dermatitis. PruMyx Cream helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Directions for Use (Rx and OTC):
Apply PruMyx Cream to the affected skin areas 3 times per day (or as needed), and massage gently into the skin. If the skin is broken, cover PruMyx Cream with a dressing of choice.

Description OTC Product:
PruMyx Cream helps to nourish skin and relieve the burning and itching associated with many common types of skin irritation. PruMyx Cream may also be used to soothe minor bums, including sunburn.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082089

(Posted November 13, 2003)